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Subject: Portland Harbor HHRA initial comments

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Attachments: PH HHRA initial comments DEQ.doc

Dana -

I did an initial review of the Draft Baseline Human Health Risk Assessment (Appendix F of the Portland Harbor Remedial Investigation Report) dated 23 September 2009. In general, the report follows the approach agreed on by the Lower Willamette Group and the agencies during discussions over the last eight years. Exposure assumptions agreed on or directed by EPA to be used were incorporated. The resulting conclusions are generally those expected by the agencies. Included in my attached comments are a few questions for EPA (shown in italics), and some issues I want to spend more time on.

My main concern is that the report contains many statements that the exposure scenarios and assumptions are overly conservative. The LWG does not agree with some of the RME scenarios, and it appears they are reluctant to use the "RME" term, perhaps because they do not consider the scenarios reasonable. In addition to inappropriate statements in the report, the LWG also submitted a letter on 8 October 2009 specifically addressing their concern about the perceived health conservatism in the risk assessment. I think this can be resolved with direction from EPA. The important point is that all major requested risks were calculated, so the agencies have the information to draw appropriate conclusions regarding risk at the site. I plan to spend more time developing a response to the question of health conservatism in the risk assessment.

An important issue for EPA is when and how to present information to the LWG on how to incorporate the breastfeeding pathway. EPA and the LWG agreed that this exposure scenario would not be included in the draft HHRA, but would be included in the final HHRA. The sooner the LWG receives direction on this issue, the sooner they can consider the implications and begin revising the report.

I'll use a specific example as an illustration of the implications, but the same results apply to every pathway with PCBs. The breastfeeding pathway is far less important for other chemicals.

From Table 5-186, the fish ingestion/multiple-species diet/fillet shows a maximum excess lifetime cancer risk (ELCR) of 6 x 10^{-3} and a maximum hazard index (HI) of 300. These values are 6,000 and 300 times the acceptable levels of ELCR = 1 x 10^{-6} and HI = 1. PCBs are the primary contributor to risk and hazard. Using the same proportions between the two endpoints (20:1), a cancer risk of 1 x 10^{-5} would correspond to a hazard index of 0.5. Both of these risk levels may be acceptable to EPA, and serve as the basis for PRGs. However, if the breastfeeding pathway is included, the HI for the infant will be approximately 20 times the HI for the mother. This increases the HI for the example pathway to about 6,000, the same level of exceedance as the cancer endpoint (this is just a coincidence). At a potential acceptable ELCR = 1 x 10^{-5} , the corresponding hazard index is now 10 instead of 1. In this case, although the ELCR falls within EPA's acceptable risk

range, the HI is unacceptable. In addition, the HI indicates a potential hot spot by DEQ, and possibly a principle threat by EPA.

We need to have internal agency discussions regarding the appropriate consideration of background in the risk assessment and feasibility study. If background PCB concentrations result in risks that are 1×10^{-5} to 1×10^{-4} (within EPA's acceptable risk range), then the corresponding HIs are 10 to 100 (clearly exceeding EPA's acceptable hazard index). Background risks may be considered unavoidable, even if they are unacceptable.

I only glanced this morning at Jim's comments on the HHRA. I expect that we will have overlap on some issues. We'll probably want to have a meeting is a couple of weeks to help you consolidate all of the agency comments.

- Mike